

REMARKS

Claims 1 – 20 are currently pending. Claims 1, 15, and 20 are the pending independent claims. In the Office Action, the Examiner rejected Claims 1 - 20 as allegedly anticipated by U.S. Patent No. 7,037,523 to Hussain et al. (“Hussain”) under 35 U.S.C. § 102(b). Claims 1, 15, and 20 have been amended in relation to the Examiner’s remarks in the Office Action. No new matter has been added by these amendments, all of which are fully supported by the specification.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

Applicants appreciate the Examiner’s modification of her position under Section 103 as described in the Office Action in the interest of advancing the case. However, Applicants must respectfully disagree with the Examiner’s characterization of their claims and with her assertions in regard to Applicants’ claim scope and in regard to the disclosure/teachings of Hussain.

As originally filed, Claims 1, 15, and 20 called for, *inter alia*, at least one pharmaceutically acceptable hydrophilic polymer in specifically defined amounts and with specific characteristics, including a relatively low viscosity. To the extent, if any, that it was not clear from the original claim language, Claims 1, 15, and 20 have been amended to now make it abundantly clear that the pharmaceutically acceptable, relatively low viscosity polymer is both hydrophilic and water-soluble. Applicants do not believe it is reasonably necessary as a matter of common sense or for purposes of claiming their invention in compliance with the Patent Act to redundantly specify that the material is both “water-soluble” and “hydrophilic.” As is apparent from the specification, Applicants intended by use of the term “hydrophilic” to specific polymers that exhibit appreciable solubility in aqueous media.

In view of the above, it should now be even more apparent that Hussain cannot reasonably be said to anticipate any of Applicants’ claims, all of which now explicitly require, among other things, a water-soluble polymer component in an amount greater than about 10 weight percent relative to the weight of the overall composition. Hussain describes pharmaceutical compositions which use water *insoluble* polymers such as ethyl cellulose. *See, e.g.*, Hussain, Col. 4, lines 30 – 33 and Col. 5, lines 39 – 47. In contrast to the claimed

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invention, Hussain seeks to avoid aqueous solubility in a pharmaceutical composition. The maximum amount of any potentially water-soluble polymer in Hussain is said to be 10 weight percent, and even this is characterized dismissively as an *optional* binding agent. According to Hussain, the processing of compositions containing such polymers “is difficult.” Hussain, Col. 2, lines 47 – 49. Therefore, Hussain very plainly cannot be said to anticipate the independent claims of the present application. Again, the present claims now explicitly require a water-soluble polymer in an amount greater than about 10 weight percent. This does not read on Hussain’s disclosure and, in point of fact, the basic orientation of Hussain is in a direction leading away from that taken by Applicants as defined in Claims 1, 15, and 20.

In light of the foregoing, Applicants respectfully request the Examiner reconsider the application, withdraw the rejections, and issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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Date: July 30, 2008
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